**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | | |
|---|---|---|
| HELEN MCLAUGHLIN, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| vs. | ) | Civil Action No._____ |
| | ) | |
| BAYER, CORP., | ) | |
| BAYER HEALTHCARE LLC., | ) | |
| BAYER ESSURE, INC., | ) | |
| BAYER HEALTHCARE | ) | |
| PHARMACEUTICALS, INC., and | ) | |
| BAYER A.G., | ) | |
| | ) | |
| Defendants. | ) | |

**NOTICE OF REMOVAL**

Defendant, Bayer Corporation (hereinafter "Defendant"), by and through its undersigned counsel, hereby provides notice pursuant to 28 U.S.C. § 1446 of the removal of the above-captioned case from the Court of Common Pleas of Philadelphia County, Pennsylvania to the United States District Court for the Eastern District of Pennsylvania. The grounds for this removal are as follows:

1. Plaintiff Helen McLaughlin commenced this action by filing a Complaint (the "Complaint") on or about November 21, 2014 in the Court of Common Pleas of Philadelphia County, Pennsylvania and the case was assigned to docket number 002423 of the November 2014 Term.

2. Plaintiff served copies of the Complaint and Notice to Defend on Defendant on December 10, 2014 via process server. True and correct copies of the Complaint, Notice to Defend, and Exhibits to the Complaint are attached hereto as Exhibit A.

3. The Complaint also names the following additional defendants: Bayer HealthCare Pharmaceuticals Inc.; Bayer Essure, Inc.; Bayer HealthCare, LLC; and Bayer AG (collectively, with Defendant Bayer Corporation, the "Bayer Defendants"). As of the date of this Notice, upon information and belief, none of the Bayer Defendants except Bayer Corporation have been served. Therefore, their consent to removal is not required. *See* 28 U.S.C. § 1446(b)(2)(A).

4. The remaining documents which have been filed in the state court action, including the Affidavit of Service on Bayer Corporation and Praecipe to Reinstate Complaint, are attached hereto as Exhibit B. A true and correct copy of the Philadelphia Court of Common Pleas docket is attached hereto as Exhibit C.

5. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of service of the Complaint and the Notice to Defend upon Defendant. Because Defendant was served on December 10, 2014 and is filing this Notice on December 30, 2014, removal is timely.

6. The time for Defendant to answer, move, or otherwise plead with respect to the Complaint has not yet expired.

7. Concurrent with the filing of this Notice, Defendant is serving this Notice on Plaintiff's counsel and filing a copy with the Office of the Prothonotary for the Court of Common Pleas of Philadelphia County, Pennsylvania.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 118(a) and 1441(a) because the United States District Court for the Eastern District of Pennsylvania is the federal judicial district encompassing the Court of Common Pleas of Philadelphia County, Pennsylvania, where this action was originally filed.

9. By filing a Notice of Removal in this matter, Defendant does not waive any of its rights to object to service of process, the sufficiency of process, jurisdiction over the person, or

venue, and Defendant specifically reserves its rights to assert any defenses and/or objections to which it may be entitled.

10. As more fully discussed below, this case is removable to federal court because there is federal question jurisdiction under 28 U.S.C. § 1331.

**FEDERAL QUESTION JURISDICTION**

11. Defendant incorporates by reference paragraphs 1 through 10 above herein as if fully restated herein.

12. Under 28 U.S.C. § 1331, the district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331.

13. Here, Plaintiff alleges various injuries as a result of her receiving a female birth control device known as Essure® System for Permanent Birth Control ("Essure"). *See, e.g.,* Complaint at ¶¶ 13-14, 85-92. Essure is a medical device as that term is defined under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c, *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* *See also* 21 U.S.C. § 321(h) and 360c(a)(1)(C)(ii). The Food and Drug Administration (the "FDA") regulates medical devices in the United States and it is responsible for implementation and enforcement of statutes and regulations pertaining to medical devices, including Essure. *Id.*

14. Federal regulation of medical devices is governed by the MDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The MDA establishes three classes of increasingly stringent federal oversight. *Id.* at 316-17.

15. "Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight." *Id.* at 316.

16. "Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject to 'special controls' such as performance standards and postmarket surveillance measures." *Id.* at 316-17 (citing § 360c(a)(1)(B)).

17. Only devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Class III devices "receiv[e] the most federal oversight" and innovative Class III devices must go through "a rigorous regime of premarket approval" before they may be brought to market, *Riegel*, 552 U.S. at 317, and are the most regulated medical devices. Class III devices are those for which performance standards (Class II) or general controls (Class I) are not sufficient assurance that the device is safe and effective for its intended use. As a result, under Section 515 of the MDA, all devices placed into Class III are subject to premarket approval requirements—a required process of scientific review designed to ensure the safety and effectiveness of Class III devices. 21 U.S.C. § 515; *see also Riegel*, 552 U.S. at 318-19.[1]

18. Essure is a Class III medical device whose design, manufacturing method, and labeling were given specific premarket approval ("PMA") by the FDA pursuant to the agency's PMA process. See Complaint at ¶¶ 15, 46-48 (*see also* U.S. Food & Drug Admin., *Premarket Approval Order for the Essure® System*, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf; last visited December 18, 2014).[2]

---

[1] The FDA's public website offers further information regarding the premarket approval process under the MDA. *See* http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm; last visited December 18, 2014.

[2] This web page is part of the FDA's public database of premarket approvals, which is accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. This Court may take judicial notice of the fact of Essure's premarket approval because the FDA's public website is a database maintained by the FDA in the normal course of its business and reflects final agency action. FED. R. EVID. 201; *see, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011)

19. Under the PMA process, a device can be approved, not approved, or issued an approvable letter. *See* 21 U.S.C. § 360e(d); *see also* Complaint at ¶ 52. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. (*See http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm*; last visited December 18, 2014).

20. The PMA process for Class III devices is the most exacting form of FDA review. To obtain FDA approval via the PMA process, a manufacturer must:

> [S]ubmit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

*Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008)). The FDA rigorously scrutinizes PMA applications, "'weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). "The FDA spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)).

21. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing

---

(affirming judicial notice of PMA approval); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012) (taking judicial notice of FDA approval documents).

processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

22. Section 360k(a) of the MDA expressly preempts any state-law claim that would impose a requirement that is "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321-28. Through this provision, Congress expressly preempted state-law tort claims challenging the design, manufacture, or labeling of a medical device previously approved by the FDA under the PMA process.

23. Conceptus, Inc. originally obtained the PMA for Essure in 2002[3].

24. Plaintiff alleges that the Bayer Defendants'[4] conduct somehow invalidated the PMA for the Essure device and, as a result, the product became "adulterated" as defined and regulated by the FDA due to the Bayer Defendants' alleged failure to comply with the PMA order and federal regulations and hence cannot be lawfully sold. *See* Complaint at ¶¶ 15–18.

25. Plaintiff's allegations center on the validity of the PMA, an order issued by the FDA, a federal agency, and the federal statutes and regulations which the FDA implements and enforces. Complaint at ¶¶ 15-26. Moreover, Plaintiff alleges that, as a result of the Bayer Defendants' failure to comply with an FDA issued PMA approval order and FDA regulations, the PMA issued by the FDA for Essure is rendered "invalid." *Id.* at ¶ 64. This allegation directly attacks the PMA, a federal order which the FDA has never found to be invalid. The PMA is still in place.[5] Plaintiff's allegations challenge the entire federal regulatory process under which the

---

[3] U.S. Food & Drug Admin., *Premarket Approval Order for the Essure® System*, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf; last visited December 18, 2014.

[4] The stock of Conceptus, Inc. was acquired by a subsidiary of defendant Bayer HealthCare LLC in 2013. *Id.* at ¶ 46.

[5] The FDA's public database for PMA approvals contains a full and complete record of the status of the PMA for the Essure device since its approval in 2002 and any supplements to the approval since that time. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4831; last visited December 18, 2014.

FDA approves Class III medical devices and attempts to substitute her own interpretation, and that of the Philadelphia Court of Common Pleas, of the FDA's approval regimen for that of the FDA.

26. Specifically, the Bayer Defendants' purported activities by: (1) failing to meet regular reporting requirements; (2) failing to report known hazards to the FDA; and (3) failing to comply with federal laws regarding marketing and distribution of the device, all allegedly invalidated the PMA making distribution of the Essure device and sale to the Plaintiff illegal under the FDCA, 21 U.S.C. §§ 301, *et seq.*, and the MDA. *See* Complaint at ¶¶ 15-20, 27-28, 51, 54–55, 59-64.

27. Plaintiff further alleges that the purportedly invalid PMA was not properly transferred from Conceptus, Inc. to the Bayer Defendants, and, therefore, the Bayer Defendants did not have any form of PMA from the FDA, making their sale and distribution of the device illegal under federal statutory and regulatory law. *See, e.g.,* Complaint at ¶¶ 62-64.

28. The federal statutes relied on by Plaintiff include the FDCA and the MDA, generally, and specifically §§ 501(f), 502(q) and (r) of the FDCA. *See* Complaint at ¶ 16, 21, 25, 59, 60, 61, 82, 100, 153, 202.

29. Thus, while Plaintiff's claims against the Bayer Defendants are purportedly pleaded under state law,[6] each claim is necessarily predicated on alleged breaches of duties imposed by federal law and challenges the safety and effectiveness of a device subject to pervasive federal regulation and administrative oversight. Indeed, her Complaint seeks to invalidate a federal order and override the discretion of the FDA. The ultimate merit of Plaintiff's causes of action will depend on Plaintiff's ability to establish a violation of relevant federal requirements on the Essure

[6] Defendant in no way concedes that any of Plaintiff's claims are cognizable as a matter of state law.

device that is causally linked to her alleged injuries. Accordingly, violation of federal law is a critical and indispensable element of Plaintiff's claims.

30. A claim may arise under federal law in either of two ways – (1) federal question by pleading a cause of action created by federal law and (2) where the claims at issue implicate significant federal issues giving rise to a substantial federal question. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). The second form of federal-question jurisdiction "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.*

31. When evaluating whether a federal statute creates a substantial federal interest giving rise to federal-question jurisdiction over claims pleaded under state law, the Supreme Court has "disclaimed the adoption of any bright-line rule." *Id.* at 317. "Instead, the question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314; *see also Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 568 (6th Cir. 2007) (en banc). This question requires courts to make "'sensitive judgments about congressional intent.'" *Id.* at 318; *accord Mikulski*, 501 F.3d at 561 ("our inquiry is ultimately one of congressional intent").

32. By enacting the MDA, Congress both recognized and reinforced a substantial federal interest in the regulation of PMA-approved Class III medical devices. Indeed, as the Supreme Court explained in *Riegel,* the very purpose of the MDA was to "swe[ep] back some state obligations and impose[] a regime of detailed federal oversight." 552 U.S. at 316. Just as Congress

took the regulation of medical devices out of the hands of state legislatures and entrusted it instead to the exclusive authority of an expert federal agency, namely the FDA, so too Congress presumably wanted the litigation of medical device claims involving innovative Class III medical devices, the most complex devices subject to the most detailed federal oversight, to be removable from state courts so that such litigation could proceed under the eye of the federal judiciary. Indeed, it would be peculiar for Congress to have "imposed a regime of detailed federal oversight," (*id.*), while at the same time preventing removal to federal court of claims predicated on the purported violation of federal requirements established by that regulatory regime.

33. Although a plaintiff suing for an injury allegedly caused by an FDA-approved medical device may still attempt to recite a cause of action nominally recognized under state law, to plead and prove a non-preempted "parallel" claim "[t]he plaintiff must be suing for conduct that violates the FDCA (or else her claim is expressly preempted by § 360k(a))." *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Thus, for a claim to escape express preemption, the duty at issue must necessarily be one imposed by federal law.

34. Because a federal duty and requirement is inevitably at issue and is in fact a required element of Plaintiff's claims, the resolution of such claims necessarily "implicate[s] significant federal issues" and "turn[s] on substantial questions of federal law." *Grable*, 545 U.S. at 312. In an analogous case, a New York district court held that a state-law negligence and product-liability action against generic drug manufacturers "necessarily raises a federal question" because, to avoid preemption, the plaintiffs were required to prove a violation of the "ongoing federal duty of sameness" under the Hatch-Waxman Act. *Bowdrie v. Sun Pharm. Indus.*, 909 F.Supp.2d 179, 183 (E.D.N.Y. 2012) (citation omitted); *see also Riegel*, 552 U.S. at 316, 322-24.

35. There can be no question that the federal question raised by Plaintiff's purportedly parallel claims is substantial. The question of whether Plaintiff can establish a violation of a federal duty that parallels her state-law claims is likely to be "dispositive of this case." *Mikulski*, 501 F.3d at 571; *see, e.g., Landers v. Morgan Asset Mgmt., Inc.*, 2009 WL 962689, at *8 (W.D. Tenn. 2009) (finding a substantial federal question where plaintiffs' negligence claim necessarily "depends on a finding that the Defendants did not meet the standard of care imposed by federal…law"). Indeed, Congress, through the MDA's express preemption clause, has specifically barred claims against medical device manufacturers including the sort of claims asserted by Plaintiff unless Plaintiff can plead and prove the violation of a parallel federal-law duty.

36. Moreover, the enforcement of the federal duties at issue here is committed to the broad oversight of the FDA, a federal agency. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (describing the "variety of enforcement options" available to the FDA). As the Sixth Circuit has recognized, the role of a federal agency, such as the involvement of the FDA in the regulation of Class III medical devices, is a factor supporting the substantiality of the federal interest. *Mikulski*, 501 F.3d at 570. Regulation of the design, manufacture, and labeling of PMA-approved medical devices is in the first instance, and primarily, federal.

37. As the Supreme Court has authoritatively recognized, the text of the MDA demonstrates Congress' intent to displace "the tort law of 50 States" and "impose[] a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316, 326; *see also Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

38. To this end, a district court's federal jurisdiction over claims concerning Class III medical devices that have received premarket approval from the FDA would not risk opening the federal courts to a flood of litigation as there is no danger here that the FDCA "would attract[] a

horde of original filings and removal cases raising other state claims with embedded federal issues." *Grable,* 545 U.S. at 318.

39. The federal interest recognized by the MDA is implicated only by claims concerning Class III medical devices that have received premarket approval from the FDA. Such devices constitute a small fraction of a small subset of medical devices. Only devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Only a relatively small number of medical devices fall into that category. And of those that do, "only a small percentage" are subject to the premarket approval process. *Smith v. Phoenix Seating Systems, LLC*, 894 F.Supp.2d 1088, 1097 (S.D. Ill. 2012). Indeed, "[t]he vast majority of Class III medical devices…reach the market without ever going through the rigorous PMA process." *Riegel*, 451 F.3d at 111.[7]

40. For these reasons, there is no danger that this Court's exercise of federal jurisdiction over claims concerning a Class III medical device with premarket approval will have any significant impact on the workload of the federal courts; rather, it "will portend only a microscopic effect on the federal–state division of labor." *Grable*, 545 U.S. at 315. Federal jurisdiction over this narrow class of cases concerning PMA-approved Class III medical devices under the MDA is

[7] "Most new Class III devices enter the market through" what "is known as the § 510(k) process," a far less rigorous process that does not trigger preemption under § 360k(a). *Riegel*, 552 U.S. at 317. "In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Id.* (citing P. Hutt, R. Merrill, & L. Grossman, FOOD AND DRUG LAW 992 (3d ed. 2007)). "In other words, in 2005, approximately ninety-nine percent of such devices went through the § 510(k) process and ***only one percent*** went through the PMA process." *Riegel*, 451 F.3d at 112 (emphasis added). In 2011, only 51 devices received premarket approval.
*See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsand Clearances/Recently-ApprovedDevices/default.htm; last visited December 18, 2014.

therefore fully "consistent with congressional judgment about the sound division of labor between state and federal courts." *Id.* at 313.

41. By enacting the MDA, Congress declared that medical devices are to be governed exclusively by requirements of federal law that are administered and enforced exclusively by the expert decisions of the FDA, a federal agency.

42. In her Complaint, Plaintiff claims that the FDA-issued PMA is "invalid." That is, she claims that the FDA's rigorous federal safety review of a Class III device – which commands the federal agency's highest standard of review – can be challenged many years after approval in a state court. Moreover and telling to the substantial federal questions she presents, Plaintiff contends that the decision reached by the FDA in approving Essure under its rigorous regulatory scheme can be invalidated by a state court under state law. This is a substantial and important federal question involving a federal agency (the FDA) and compliance with federal statutes and regulations. There is no question that Plaintiff's tort claims, which challenge the safety and effectiveness of such a Class III medical device and invoke federal statutory and regulatory requirements related to such devices, implicate substantial federal interests that call for the availability of jurisdiction in a federal forum.

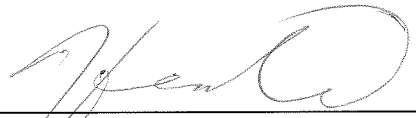
43. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. § 1331, and this case is removable under 28 U.S.C. § 1441.

WHEREFORE, Notice is given that this action is removed from the Court of Common Pleas of Philadelphia County, Pennsylvania to the United States District Court for the Eastern District of Pennsylvania.

Dated: December 30, 2014

Respectfully submitted,

**ECKERT SEAMANS CHERIN & MELLOTT LLC**



ALBERT G. BIXLER, ESQUIRE
LESLIE A. HAYES, ESQUIRE
MARK C. LEVY, ESQUIRE
HEATHER R. OLSON, ESQUIRE
Pa I.D. Nos. 45639, 35975, 42234, & 92073
Two Liberty Place
50 South 16th Street, 22nd Floor
Philadelphia, PA 19102
Phone: 215-851-8400/Fax: 215-851-8383
abixler@eckertseamans.com
lhayes@eckertseamans.com
mlevy@eckertseamans.com
holson@eckertseamans.com

*Attorneys for Defendant Bayer Corporation*

## CERTIFICATE OF SERVICE

I, HEATHER R. OLSON, do hereby certify that, on December 30, 2014, I caused a true and correct copy of the foregoing Notice of Removal to be served upon the following counsel of record, in the manner indicated:

***Via Hand Delivery and Electronic Mail***

James J. McEldrew, III, Esquire
Thomas A. Dinan, Esquire
McELDREW LAW, LLC
123 South Broad Street, Suite 1920
Philadelphia, PA 19109
215/545-8800
jim@mceldrewlaw.com
tdinan@mceldrewlaw.com

***Via U.S. First Class Mail and Electronic Mail***

Marcus Susen, Esquire
Justin Parafinczuk, Esquire
KOCH PARAFINCZUK & WOLF
110 E. Broward Blvd., Suite 1630
Fort Lauderdale, FL 33301
954/462-6700
susen@kpwlaw.com
parafinczuk@kpwlaw.com

***Attorneys for Plaintiff***

HEATHER R. OLSON

M1320804